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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/963,237	09/26/2001	David Ringshaw	PC9472B	9382

7590 06/16/2003

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EXAMINER
OWENS JR, HOWARD V

ART UNIT	PAPER NUMBER
1623	7

DATE MAILED: 06/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/963,237	Applicant(s) RINGSHAW ET AL.	
	Examiner Howard V Owens	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 April 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Response to Arguments

The following is in response to the amendment filed 4/7/03:

An action on the merits of claims 1-5 is contained herein below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

35 U.S.C. § 112

The rejection of claims 2-5 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been overcome through applicant's amendment to the claims specifying the compounds that define the term "organic radical".

35 U.S.C. § 103

Applicant's arguments filed 4-7-03 have been fully considered but they are not persuasive. The rejection of claims 1-5 under 35 U.S.C. 103(a) as being unpatentable over Loftsson, U.S. 5,472,954 in combination with Asato et al. (Asato), U.S. 4,886,829 is maintained for the reasons of record.

Claims 1-5 are drawn to a composition comprising at least one anthelmintically active compound which is an avermectin,milbemycin or compound of formula I complexed with at least one cyclodextrin.

Asato teaches the compound of formula I and also teaches that compounds of this formula are antihelmintic compounds which may be formulated in liquid or solid form for infestation in warm blooded animals and agriculture. However, Asato does not teach the combination of the antihelminthic compound with cyclodextrin.

Loftsson bridges the nexus for the use of cyclodextrin with antihelmintic compounds as it teaches that antihelmintic compounds—such as ivermectin, avermectin, and milbemycin--can complex with cyclodextrin(See column 8, lines 49 - 50) and that cyclodextrins have been used in the art to increase the stability of drugs and agrochemicals when complexed therewith (col.1-col.2). Loftsson also teaches that "solid pharmaceutical preparations, made, for example by removal of water from the above mentioned aqueous cyclodextrin polymer drug solutions, for example by lyophilization, are characterized by faster and more efficient dissolution of drugs compared to the dissolution of drugs from solid cyclodextrin preparations without polymers. This can lead to hastening the onset of the therapeutic response and can also increase the total bioavailability of drugs from solid pharmaceutical preparations (col. 15, lines 43-51)." Loftsson does not specifically teach the use of the compound of formula I with a cyclodextrin, however.

It would have been *prima facie* obvious to the person of ordinary skill in the art at the time of the invention to have complexed a cyclodextrin with an antihelmintic.

One of skill in the art would have been motivated to combine an antihelminthic with a cyclodextrin for the purpose of obtaining a complex with improved water solubility over the uncomplexed drug while maintaining the biological activity of said drug.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In the case of the instant claims, the combination of an antihelminthic compound and cyclodextrin was gleaned from the prior art of Asato, not applicant's disclosure.

Applicant states that because the examiner stated the deficiency of Loftsson, the 35 burden for obviousness was not met. Applicant should note that if the Loftsson reference contained all of the elements of the claim, than a 35 U.S.C. 102 would be

applicable. The examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the compounds are known, thus a reasonable motivation for the combination of the antihelminthic compound and cyclodextrin supported by the prior art was required. As cited supra, Loftsson bridges the nexus for the use of cyclodextrin with antihelmintic compounds as it teaches that antihelmintic compounds—such as ivermectin, avermectin, and milbemycin--can complex with cyclodextrin(See column 8, lines 49 - 50) and that cyclodextrins have been used in the art to increase the stability of drugs and agrochemicals when complexed therewith (col.1-col.2). Applicant has not provided a response as to how the teachings of Loftsson with regard to the combination of the antihelminthic compound (such as those claimed) with cyclodextrin for increased stability is not a reasonable motivation; moreover, applicant's claim to superior results is not persuasive, given that the prior art of Loftsson previously recognized the increased stability of antihelminthic compounds when complexed with cyclodextrin over uncomplexed compounds. Thus any data that applicant presents showing an increase in stability with regards to degradation of the cylcodextrin complexed antihelminthic compound is redundant to the teachings of the prior art. Applicant's statements regarding the omission of an element and retention of it's function as an indicia of obviousness is also not persuasive given that Loftsson does not solely target a water soluble polymer, as stated by applicant, Loftsson teaches "...the complexation of a cyclodextrin with a lipophilic (emphasis added) and/or water labile active ingredient". Thus Loftsson is clearly indicating that the cyclodextrin may be complexed with lipophilic compounds, water soluble compounds or a combination of the two, clearly demonstrating that the invention is not limited to the lone embodiment of a water soluble polymer.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Howard V. Owens
Patent Examiner
Art Unit 1623

James O. Wilson
Supervisory Patent Examiner
Technology Center 1600

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Howard Owens whose telephone number is (703) 306-4538 . The examiner can normally be reached on Mon.-Fri. from 8:30 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the Supervisory Patent Examiner signing this action, James O. Wilson can be reached on (703) 308-4624 . The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.